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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,421	01/22/2001	Michael J. Shamblott	JHU1750-1	9551

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/767,421	SHAMBLOTT ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election of group I, claims 1-32, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-33 are pending. Claims 1-32 are examined below. Claim 33 is withdrawn from consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of "embryoid body-derived cell culture" are not clear. As all cells of the body are derived from germ layers of the embryoid body, a primary culture of a particular tissue would contain such cells. For example, in a primary culture of myocytes, there might be cells from the facie or blood vessel cells. In this regard, the cell culture would contain cells derived from multiple germ layers and have markers of a cell of particular origin. The claims encompass the markers being specific for cells of different germ layers or any cells that differentiate from particular germ layers. For example, the claim encompasses a culture comprising cells from the mesodermal germ layer as well as a muscle cell and cells from the endodermal germ layer as well as fibroblast cells. Applicant might consider changing the wording to the claim to "a cell culture of human embryoid body cells comprising ....." if that is indeed what applicant means to claim.

Claims 26 and 26 contain the trademark/trade name EGM2MV. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second

paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a tissue culture media supplement and, accordingly, the identification/description is indefinite. EGM2MV appears to be a trademark for Clonetics, San Diego. Also see the specification, page 17, line 19.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 11 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by Shamblott et al (1998) Proc. Natl. Acad. Sci. 95, 13726-13731.

The claims are to a human embryoid body-derived cell culture. Shamblott teaches the formation of embryoid bodies by the culture of human primordial germ cells and the formation of embryoid bodies (page 13727, col. 1, parag. 2, lines 1-4 and page 13729, col. 1, parag. 3, lines 1-3). The formation of embryoid bodies in Shamblott creates an embryoid body-derived cell culture as further culture of the embryoid bodies would produce additional embryoid body cells derived from the nascent embryoid body. The embryoid bodies of Shamblott were shown to form the three germ layers, endoderm, mesoderm and ectoderm using specific markers for each layer, α-fetoprotein being an endodermal marker (page 13729, col. 1, Table 1 and col. 2, parag. 1, lines 1-3). Shamblott teaches the culture of EB's in the absence of LIF (page 13727, col. 1, parag. 3, lines 1-4). Any culture of EB's in

Shamblott would inherently so culture embryoid body derived cells. Thus Shamblott clearly anticipates the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shamblott et al (1998) Proc. Natl. Acad. Sci. 95, 13726-13731.

Shamblott teaches the formation of embryoid bodies by the culture of human primordial germ cells and the formation of embryoid bodies (page 13727, col. 1, parag. 2, lines 1-4 and page 13729, col. 1, parag. 3, lines 1-3). The embryoid bodies of Shamblott were shown to form the three germ layers, endoderm, mesoderm and ectoderm using specific markers for each layer, α-fetoprotein being an endodermal marker (page 13729, col. 1, Table 1 and col. 2, parag. 1, lines 1-3). As Shamblott taught the expression of multiple germ layer markers in the human EB's disclosed, it would be obvious that the human EB's and specific human EB cells would also express other known germ layer markers. Thus, at the time of the instant invention, it would have been obvious to the ordinary artisan that the claimed EB derived cell cultures would have expressed the specific germ layer markers claimed given the multiple marker expression taught by Shamblott.

Claims 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shamblott et al (1998) Proc. Natl. Acad. Sci. 95, 13726-13731.

Shamblott teaches the formation of embryoid bodies by the culture of human primordial germ cells and the formation of embryoid bodies (page 13727, col. 1, parag. 2,

lines 1-4 and page 13729, col. 1, parag. 3, lines 1-3). The art at the time of filing taught methods of transfection, and lentivirus and retrovirus were known vectors at the time of filing. Further, the art also taught methods of cloning. Thus given the teachings of Shamblott in view of the teachings in the art, it would have been obvious to the ordinary artisan to transfected the EB derived cells of Shamblott or to make clonal cultures using a single cell.

Claims 9, 10, 14 and 22-32 appear to be free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Reynolds, SPE of AU 1632 whose telephone number 703-305-4051. The examiner can normally be reached on M-Th.

Should inquiries be made on or after January 12, 2004, the examiner's phone number will be 571-272-0727. Deborah Reynolds will be reached at 571-272-0734.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

D.C.
January 8, 2004